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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,438	02/10/2004	Rajeev S. Bhide	LD0329 NP	9405

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EXAMINER

OWENS, AMELIA A

ART UNIT PAPER NUMBER

1625

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/775,438

**Applicant(s)**

BHIDE, RAJEEV S.

**Examiner**

Amelia A. Owens

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8 and 10 is/are allowed.
- 6) ☒ Claim(s) 9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

Claims 1-14 are pending.

***Claim Rejections - 35 USC § 102***

The rejection under 35 USC 102(b) has been dropped as hydrogen has been deleted from variable W creating a demarcation over the art. The claimed compounds are also useful as antifungal agents. See specification page 16 lines 15-16.

Claims 1-8,10 are allowable. The prior art neither teaches nor suggests the claimed compounds.

***Claim Rejections - 35 USC § 112***

Claims 9,11-14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' remarks have been considered and are not persuasive. Applicants in their response indicate that the compounds from the data have 'potential' use for effectively inhibiting or treating cancer. For the requirements of 35 USC 112 to be met the compound must 'definitely' inhibit/treat cancer in some form, 'potential' use is not enough.

While it is well settled that testing data, working examples are not needed to fulfill the requirements of 35 USC 112, it is also well settled that where compounds are alleged to be useful to treat cancer, that utility needs to be proved. In re Bergel and Stock (CCPA 1962) 130 USPQ 206. Further, allegations in the specification of utility that are or border on the incredible in light of contemporary knowledge in the particular art must be substantiated by acceptable evidence. Arguably, treating/inhibiting cancer/tumor is no longer incredible, however, it is sufficiently

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unusual to warrant substantiating evidence. Ex parte Busse et al (BPAI 1986) 1PQ2d.

Currently, there is no umbrella compound that treats/inhibits all forms of cancer or tumor growth as presently claimed.

Further, farnesyl protein transferase (FPT) is associated with only 20-30% of all cancers. As now presented, applicants' claims are directed to 'all' cancer. See Crul et al J. clinical Oncology, 20(11), June 1, 2002, 2726-2735, page 2726. Clearly FPT is connected to a limited number of cancer/tumor growths. Crul at Table 1 tests the FPT inhibitor R11577 against select forms of cancer. Applicants in their specification at lines 6-10 mention the same forms of cancer. Again, there is no umbrella drug that treats cancer/tumor.

It is noted that the specification recites 'known' anticancer agents. However, which agents are those exactly. For the requirements of 35 USC 112 to be met applicants are required to tell the public 'what' their invention is. One of ordinary skill in the art would have to test the claimed compound in combination with 'every' known anticancer agent belonging to the *classes of anticancer agents* recited by applicant at page 17. This would seem to be undue experimentation.

Claims 9,11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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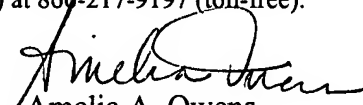
The instant method of treatment/inhibition of cancer as recited in the claims encompasses such unidentified forms of cancer/tumor growth, a description of which is not found in the specification.

The instant method of treatment/inhibition of cancer with additional anticancer agents as recited in the claims encompasses such unidentified anticancer agents, a description of which is not found in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Amelia A. Owens  
Primary Examiner  
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